

Contents lists available at ScienceDirect

Applied Ergonomics

journal homepage: www.elsevier.com/locate/apergo



Safer healthcare at home: Detecting, correcting and learning from incidents involving infusion devices



Imogen Lyons, Ann Blandford*

UCL Institute of Digital Health & UCL Interaction Centre, University College London, Gower Street, London, WC1E 6BT, UK

ARTICLE INFO

Article history: Received 13 January 2017 Received in revised form 11 September 2017 Accepted 17 September 2017

Keywords:
Patient safety
Incident reporting
Qualitative research
Primary care
Infusion devices

ABSTRACT

Objective: Complex medical devices such as infusion pumps are increasingly being used in patients' homes with little known about the impact on patient safety. Our aim was to better understand the risks to patient safety in this situation and how these risks might be minimised, by reference to incident reports.

Design: We identified 606 records of incidents associated with infusion devices that had occurred in a private home and were reported to the UK National Reporting and Learning Service (2005–2015 inclusive). We used thematic analysis to identify key themes.

Results: In this paper we focus on two emergent themes: detecting and diagnosing incidents; and locating the patient, lay caregivers and their family in incident reports. The majority of incidents were attributed to device malfunction, and resulted in the patient being under-dosed. Delays in recognising and responding to problems were identified, alongside challenges in identifying the cause. We propose a process model for fault diagnosis and correction.

Patients and caregivers did not feature strongly in reports; we highlight how the device is *in* the home but *of* the care system, and propose an agent model to describe this; we also identify ways of mitigating this disjoint.

Conclusion: Devices need to be appropriately tailored to the setting in which they are employed, and within a system of care that ensures they are used optimally and safely. Suggested features to improve patient safety include devices that can provide better feedback to identify problems and support resolution, alongside greater monitoring and technical support by care providers for both patients and frontline professionals. The proposed process and agent models provide a structure for reviewing safety and learning from incidents in home health care.

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1. Introduction

Globally, there is a trend toward healthcare in the home rather than hospital (NRC, 2011; RCN, 2014). Changing patient demographics, patient preferences, economic pressures to reduce hospital admissions and length of stay, along with medical and technological advances, have all contributed to the growth of home care. Alongside growing numbers of patients receiving care for chronic conditions, earlier hospital discharge has increased the acuity of homecare patients (Lang et al., 2008). Consequently, complex medical devices such as infusion pumps, feeding pumps,

ventilators, etc., often designed for use by trained professionals in clinical settings, are increasingly used in the home (Leff and Burton, 2001; NRC, 2011; Beer et al., 2014). As well as bringing benefits, these advances pose challenges for safety and effectiveness, and bring new risks (Weick-Brady and Lazerow, 2006). The aim of the work reported here was to better understand how safety is managed when infusion devices are deployed in people's homes.

2. Background

The home environment differs from the hospital in important ways (NRC, 2011). Typically, patients and caregivers are left alone with medical devices for lengthy periods with limited, if any, training. Consequently, technical or clinical problems may not be as promptly identified and resolved as in hospital, where patients are continuously monitored (Hilbers et al., 2013). Furthermore, home

^{*} Corresponding author.

E-mail addresses: imogenclyons@gmail.com (I. Lyons), A.Blandford@ucl.ac.uk
(A. Blandford).

healthcare professionals (HCPs) work in relative isolation, without immediate supervision or support, and often lack timely, convenient access to equipment and resources (Lang et al., 2008). They typically visit the home singly, or occasionally in pairs, and are responsible for all aspects of a patient's nursing care; thus, the HCP is responsible for the effective operation of all devices needed to support a patient at home. However, they may have insufficient opportunities to develop skills with all the devices they encounter (Hilbers et al., 2013).

Despite the growing prevalence of home healthcare, patient safety research and human factors research in healthcare focus predominantly on institutional settings (Macdonald et al., 2013; Valdez et al., 2017; Werner et al., 2017). Some researchers have suggested that the less structured nature of home care carries more potential for adverse events than traditional care settings (Masotti et al., 2010). There is, therefore, a need to better understand medical device use in private homes and how people manage when things go wrong.

Beer et al. (2014) report on challenges experienced by home health care workers, considering a range of tasks (from wound care and bathing through to managing infusion administration). They relate their findings to a model of human factors for health care in the home that centres on the people, tasks and equipment involved in home care. For infusion devices, the main challenges identified by Beer et al. relate to set-up (e.g., clearing air from the line) and troubleshooting; they highlight the need for more instructional material and better training in these areas, and advocate standardisation of equipment as far as possible, to minimise the number of devices each HCP needs to be familiar with. Vincent and Blandford (2017) describe the work of home nurses, particularly focusing on the use of ambulatory syringe drivers for palliative care; they highlight the adaptations that caregivers have to make so that devices are fit for purpose in the home setting and when patients are outdoors. The main safety feature discussed is the design and use of a lockbox so that only designated health care professionals can access the device. However, neither of these studies focused specifically on how HCPs manage device failures or recover from incidents involving infusion devices (or similar technology).

Others (e.g., Carayon et al., 2014; Wooldridge et al., 2017) have advocated taking a human factors systems approach to patient safety. They focus on describing the work system, the processes involved in care, and the outcomes. Their focus is on the overall system, and designing it to improve quality; this is a broader question than that which we address in this paper. In this study, we also adopt a human factors systems approach, but focus on the causes of and recovery from incidents involving infusion devices that occur in home health care. We propose process and agent models that encapsulate key phenomena and support reasoning about patient safety in this context.

In this study we examined incidents related to infusion device use in private homes, reported to the UK National Reporting and Learning System (NRLS). While in principle the NRLS accepts reports from anyone, in practice nearly all reports are submitted by HCPs (including all the reports analysed in this study). We focused on infusion pumps because they have previously been identified as a common cause of problems (Beer et al., 2014), are safety-critical, and have been found to feature in more reports of incidents at home than any other device (NRC, 2011). While the most common use of infusion pumps at home is for palliative care near end of life, they are increasingly being used at home to deliver other medications: e.g., for the management of long term conditions. Our aim was to explore the characteristics of reported incidents associated with infusion devices, and the circumstances surrounding their causes, detection and resolution, to inform the design of future devices and the systems of care in which they are used.

3. Methods

Since this study involved the use of anonymised records where permission had been obtained from the data provider (data sharing agreement 002.13.DSA.UCL) and it was not possible to identify individuals from the information provided, it was determined that the study complied with exemption 2 under the UCL code of ethics (https://ethics.grad.ucl.ac.uk/exemptions.php).

3.1. Study design and context

We undertook a retrospective analysis of data from the NRLS, which records patient safety incidents within NHS organisations in England and Wales. The NRLS has defined a patient safety incident as any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare (NPSA, 2011). Staff typically submit reports via a local reporting system; these are subsequently uploaded to the NRLS (Panesar et al., 2009; Thomas and Panchagnula, 2008). The list of recognised incident types is long, from "Absconder/missing patient" to "Unplanned return to theatre" (NRLS, n.d.). Thus, the NRLS is a comprehensive source of incident reports, covering all healthcare settings across England.

3.2. Search strategy and sample selection

17,741 anonymised reports from the NRLS were retrieved (see Appendix A for search terms). The search covered 1st January 2005 to 31st December 2015. The data was provided as an Excel spreadsheet; each record comprised 25 data items. Of these items, two were identifiers (organisation and incident number); 16 had originally been entered as a selection from a menu (defining date, location, incident type, etc.) and the remaining seven were free text fields (enabling the reporter to add details). The majority of incidents reviewed in this study were classified as "Medication" or "Medical device/equipment" incident types.

We selected all 982 incidents categorised as occurring in a "private house, flat, etc." These reports were reviewed; 177 were excluded as the incident was not associated with an infusion device or did not occur in a private home; six duplicates were also excluded, leaving 799 reports, each relating to a unique incident.

3.3. Data analysis

Our analysis focussed on data from three of the free text fields: 'Description of what happened', 'Actions Preventing Reoccurrence', and 'Apparent Causes'. While the shortest report comprised only 20 words (across all three fields), the majority were 200—500 words in total, and the longest was over 800 words.

We undertook a thematic analysis (Braun and Clarke, 2006) to identify and report important themes within the data. Analysis began by reading through each report and noting broad patterns. Since our focus was on managing patient safety in therapies involving the use of infusion devices, incidents that did not directly involve the device (e.g., prescribing errors or poor documentation of drugs in the home) were excluded. Incidents in which the patient had, or might have, received more or less medication than intended had greatest safety implications; therefore, reports on other incident types (e.g., keypad not locked) were also excluded. In total, a further 193 reports were excluded, leaving 606 reports in the final analysis. The analysis was completed by hand. We generated preliminary codes, starting with a random sample of reports, revising codes and organizing them into broader themes as further reports were reviewed. The first author conducted the analysis of reports up to 2011, with discussion of emerging themes and interpretation

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